

Claims

1. A pharmaceutical composition comprising a polytartrate polymer and at least one pharmaceutically active material characterised in that the composition is capable of releasing the pharmaceutically active material in a pulsatile manner and is obtainable by forming the tablet with a compression force between 10 and 65 kN/cm².
2. The composition according to claim 1 characterised in that the composition is formed at a compression force between 20 and 50 kN/cm².
3. The composition according to claim 1 or 2 characterised in that the polytartrate polymer forms degradation products that increase the pressure inside the composition.
4. The composition according to claim 3 characterised in that the polytartrate polymer forms during degradation a C1 to C4 alcohol, aldehyde or ester or acetone.
5. The composition according to claim 4 characterised that the polytartrate polymer forms during degradation methanol, ethanol, propanol, isopropanol or acetone.
6. The composition according to claims 1 to 5 characterised in that the polytartrate polymer is selected from the group of polycondensates of dimethyl tartrate, diethyl tartrate, diisopropyl tartrate or copolymers thereof and 2,3-O-alkylidenetartaric acid derivatives.
7. The composition according to claim 6 characterised in that the polytartrate polymer is 2' 3'- (1', 4'- diethyl) - L- tartryl poly - (2 , 3 -O-isopropylidene) -L - tartrate.
8. The composition according to any of the claims 1 to 7 characterised in that the polytartrate polymer has a glass transition temperature that is greater than 40°C.
9. The composition according to any of the claims 1 to 8 characterised in that the pharmaceutically active material is selected from one or more of antigens, antibodies or pharmaceutical substances.
10. The composition according to claim 9 characterised in that the pharmaceutically active material is a GnRH agonist.

11. The composition according to claim 10 characterised in that the pharmaceutically active material is buserelin.
12. The composition according to claim 11 characterised in that the pharmaceutically active material is azagly nafarelin.
- 5 13. The composition according to any of the claims 1 to 12 characterised in that the composition additionally comprises one or more of pharmaceutically acceptable excipients or adjuvants.
14. Process for the preparation of a polytartrate composition according to claims 1 to 13 involving the steps of
- 10 a) mixing an effective amount of a pharmaceutically active material with the polytartrate polymer,
- b) shaping the mixture by a tableting equipment to form compressed tablets by applying a compression force between 10 and 65kN/cm².
15. The process according to claim 14 characterised in that the pharmaceutically active material and the polytartrate polymer are mixed in a powdered form.
- 15 16. The process according to any of the claims 14 or 15 characterised in that the mixture is sieved and optionally additional tableting excipients are added to the mixture.